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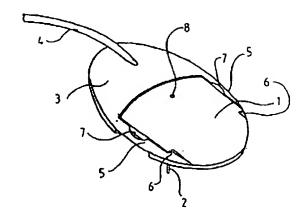
(73) Owner:

Maersk Medical A/S, lynge, DK

74) Representative

Tiedtke, Bühling, Kinne & Partner, 80336 Munich

- (54) Device for subcutaneous infusion
- (57) Device for subcutaneous infusion featuring the following:
  - a housing;
  - a flow channel inside the housing;
  - a needle attached in the housing to the flow channel in flow connection;
  - a self-sealing partition, which covers the flow channel;
  - a connection device to supply fluids to the flow channel;
  - a needle on the connection device to penetrate the self-sealing partition, which covers the flow channel;
  - an opening in the housing to insert an insertion needle;
  - a self-sealing partition to cover the opening; at which the self-sealing partition, which covers the flow channel, and the self-sealing partition, which covers the opening, consist of a single element.



# TIEDTKE --- BÜHLING --- KINNE & PARTNER (GbR)

Tiedtke -- Bühling - Kinne, POB 20 19 18, D-80019 Munich

Patent Attorneys / Representatives at EPO \*

Dipl. Ing. Harro Tiedtke\*

Dipl. Chem. Gerhard Bühling\*

Dipl. Ing. Reinhard Kinne

Dipl. Ing. Hans-Bernd Pellmann\*

Dipl. Ing. Klaus Grams\*

Dipl. Biol. Dr. Annette Link

Dipl. Ing. Aurel Vollnhals\*

Dipl. Ing. Thomas J. A. Leson\*

Dipl. Ing. Hand-Ludwig Trösch\*

Dipl. Ing. Dr. Georgi Chivarov\*

Dipl. Ing. Matthias Grill\*

Dipl. Ing. Alexander Kühn\*

Dipl. Chem. Dr. Andreas Oser\*

Dipl. Ing. Rainer Böckelen\*

Bavariaring 4, D-80336 Munich

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DE 23838 / case P199701455

## MAERSK MEDICAL A/S

Lynge, Denmark

"Device for Subcutaneous Infusion"

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DE23838

#### Title

#### Device for Subcutaneous Infusion

### Background of the Invention

The invention at hand is based on infusion devices for subcutaneous release of a drug or therapeutic fluid by means of an external infusion system and, in particular, is based on an infusion device which involves a device for the purpose of releasing the drug or therapeutic fluid that is detachably connected to the external infusion system.

The infusion systems generally known in prior art release a drug or therapeutic fluid to a subcutaneous area in a patient by means of a needle, which is inserted to the subcutaneous area through the patient's skin. Such devices usually have a tubular needle extending from a housing which is adapted to receive the desired drug via a detachable device which can be appropriately connected with other components of the infusion system. The possibility of detaching the infusion set from other components of the infusion system has been provided in order to make it more convenient for the user. The user is able to perform activities which do not allow for the presence of a pump or the like, or which are impeded by the presence of a pump or the like. In detached condition, the patient carries only part of the infusion set. This allows for more mobility. In order to provide such a detachable device and, in addition, maintain a fluid-proof sealing in the internal of the housing and tubular needle, which prevents contamination of the infusion area, such devices are usually provided with a self-sealing partition on the housing or on the detachable part and with a hollow needle on the other part which is adapted in such a way that it can penetrate the partition. As a result of extracting the needle from the partition, this provides a fluid-proof sealing toward the internal of the housing. Furthermore, the partition and the needle provide a fluid-proof sealing between the housing and the connection device, if the drug or the therapeutic fluid is dispensed from the external infusion system to the patient. Devices for subcutaneous infusion of this generally known kind are, for instance, known from the US patent 5522803 by Teissen-Simony and the US patent 5545143 by Fischell.

In connection with such infusion devices, which have various insertion places for the insertion needle and the needle of the connection device, a self-sealing partition is required at every insertion place. Because of this fact, manufacture of such devices is very inconvenient and time-consuming.

Because of their construction, the previously known infusion devices, which require a partition at each insertion place to insert a needle, need relatively much space.

For these reasons, there is a demand for improvement regarding infusion devices of the models described above and especially with regard to providing an infusion device which, from the viewpoint of manufacturing, is considerably less complicated than a device that has a fluid-proof sealing

between the housing and the connection device in an interactive attachment position for these elements. The invention-based infusion device eliminates the disadvantages described above and provides further advantages which are manifested by the following description.

#### Abstract of the Invention

According to the invention, a device for subcutaneous infusion has been developed at which the infusion device has the following features:

- a housing;
- a flow channel in the housing;
- a needle attached in the housing to the flow channel in flow connection;
- a self-sealing partition, which covers the flow channel;
- a connection device to supply fluids to the flow channel;
- a needle on the connection device to penetrate the self-sealing partition, which covers the flow channel;
- an opening in the housing to insert an insertion needle;
- a self-sealing partition to cover the opening;
- at which the self-sealing partition, which covers the flow channel, and the self-sealing partition, which covers the opening, consist of a single element.

By providing the self-sealing partition for the purpose of sealing both openings as a single element, it is possible to reduce the cost of material as well as production cost without affecting the function of the infusion device. It also makes it possible to provide an infusion device with smaller dimensions than previously known devices.

In a preferred embodiment, the housing features a part of the flow channel which produces a chamber, with the opening facing the chamber and the self-sealing partition is placed in the chamber.

A further advantage is the fact that the self-sealing partition has a surface that is inclined in relationship to the axis of the flow channel as well as to the axis through the opening and the needle.

The infusion device is advantageously connected to the patient by means of an adhesive.

With reference to the drawings, the invention is subsequently described in more detail.

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## Brief description of the drawings

Figure 1 is a perspective view of a further preferred embodiment of the invention-based device for subcutaneous infusion;

Figure 2 is a lateral view of the device shown in figure 1;

Figure 4 is a top view of the device shown in figure 1;

Figure 3 is a cross section along the line 3-3 in figure 4;

Figure 5 is a top view of the housing of the device shown in figure 1;

Figure 6 is a top view of the connection device of the device shown in figure 1;

Figure 7 is a rear view of the housing of the device shown in figure 4;

Figure 8 is a front end view of the connection device of the device shown in figure 4;

Figure 9 is a top view of the self-sealing partition;

Figure 10 is a front view of the self-sealing partition;

Figure 11 is a lateral view of the self-sealing partition;

Figure 12 is a lateral view of an insertion needle to be used in connection with the device shown in figure 1.

## Description of the preferred embodiments

Figure 1 shows that the second embodiment of the infusion device features a housing 1 and a soft needle 2 which extends from the housing. A connection device 3 is connected to the housing and a tube 4 extends from the connection device in order to provide a fluid connection between a pump (not shown) and the connection device 3. Two blocking arms 5 are provided on the connection device 3 in order to produce a block function with regard to the housing 1.

Figure 2 shows the device from a lateral point of view. It is shown that an insertion device featuring a needle bush 9 and a needle 10 are attached in the housing and through the lumen of the soft needle 2.

Figure 3 shows that the housing 1 has a drill hole at which the soft end of the needle 2 is attached to one end of the drill hole in flow connection. Opposite of the soft needle 2, a self-sealing

partition 16 is attached to the one end of the drill hole. The connection device 3 features a drill hole 13 at which the tube 4 is connected to one end of this drill hole, forming a fluid connection. At the other end of the drill hole, opposite of the tube, a hollow needle 12 is provided, forming a fluid connection with the drill hole. The needle 12 is provided to penetrate the self-sealing partition 16 in the housing. The self-sealing partition 16 provides a fluid and air seal toward the surrounding area if the needle 12 of the connection device is extracted from the partition. Said self-sealing partition also provides a fluid and air seal around the needle 12 if it is inserted through the partition.

Figure 4 shows that the device has basically an elliptic shape. However, the device could also have any other basic shape which allows for the provision of a drill hole, a self-sealing partition and a needle in the housing, and a drill hole, a tube and a needle in the connection device and, furthermore, the combined guiding and closing device 5, 6 in connection with the housing and the connection device. Each of the two blocking arms 5 on the connection device features a barbed hook 6 which interacts with one lug in the housing 1. In order to disconnect the connection device 3 and release the barbed hooks from their blocking position while the connection device 3 is extracted from the housing 1, the blocking arms 5 must be pressed together at the surface 7 which has a tapering thickness of the material.

Figure 5 shows the housing after the connection device is released from the device. It is shown that the housing 1 features a platform which extends to the rear and which is provided to support the connection device in attached condition. Grooves 18 are provided in order to ease the movement of the blocking arms toward each other during the release action of the connection device.

Figure 6 shows the connection device after being disconnected from the housing 1. This shows that the flexible blocking arms 5 extend beyond the needle 12 providing a shield against dangerous injuries caused by the needle. Each arm also provides lugs 19. These serve as guiding devices for the connection device with regard to the housing and prevent accidental movements lateral to the needle axis.

Figure 7 shows the rear end of the housing. It is shown the conical inlet to insert the needle into the element 17, as well as the grooves for the flexible guiding and blocking arms 5, 19.

Figure 8 shows the front end of the connection device 3. It shows the needle 12 and the flexible guiding and blocking arms 5.

Figure 9, figure 10 and figure 11 each show a top view, front view and lateral view of the self-sealing partition 16. On the outside, the partition 16 has the shape of an inclined, truncated cylinder. This shows that, because of the inclined, truncated shape, the partition features a surface which is conical in proportion to the flat top side and rear side. The inclined surface points to the interior of the housing and allows the insertion needle to penetrate through the soft needle and allows the needle of the connection device to be used to supply fluid to the hollow space in the interior of the housing. However, the partition can have any shape corresponding to the respective

openings of the housing and, at the same time, allowing for the penetration of the insertion needle as well as the needle of the connection device, for example a partially ball-shaped form.

Figure 12 shows an insertion needle to be used in connection with the device shown in figure 10. The insertion needle features a needle bush 9 and a needle 10 which extends in insertion position shown in figure 2 through the soft needle 2 beyond its outer tip.

The invention applies to a device for subcutaneous infusion with the following features: a housing; a flow channel in the housing; a needle attached in the housing to the flow channel in flow connection; a self-sealing partition, which covers the flow channel; a connection device to supply fluids to the flow channel; a needle on the connection device to penetrate the self-sealing partition, which covers the flow channel; an opening in the housing to insert an insertion needle; a self-sealing partition to cover the opening; at which the self-sealing partition, which covers the flow channel, and the self-sealing partition, which covers the opening, consist of a single element.

By providing the self-sealing partition for the purpose of sealing both openings as a single element, it is possible to reduce the cost of material as well as production cost without affecting the function of the infusion device.

## TIEDTKE --- BÜHLING --- KINNE & PARTNER (GbR)

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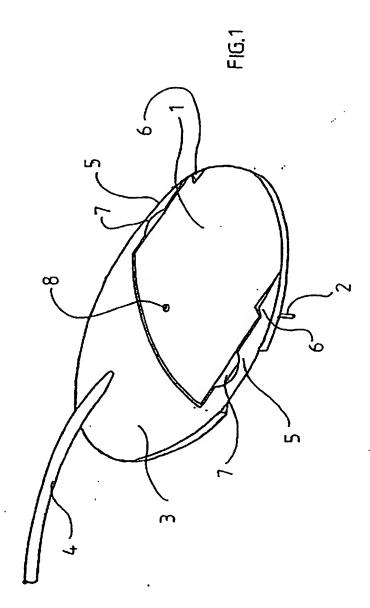
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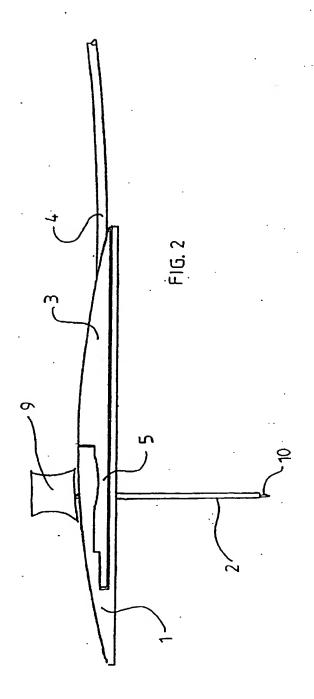
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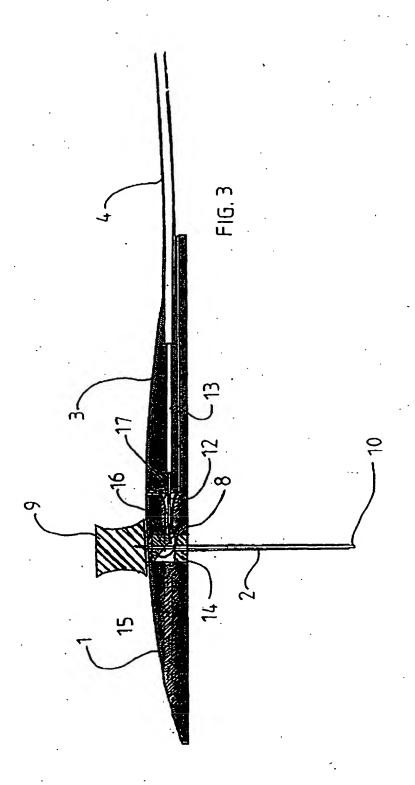
#### **Claims**

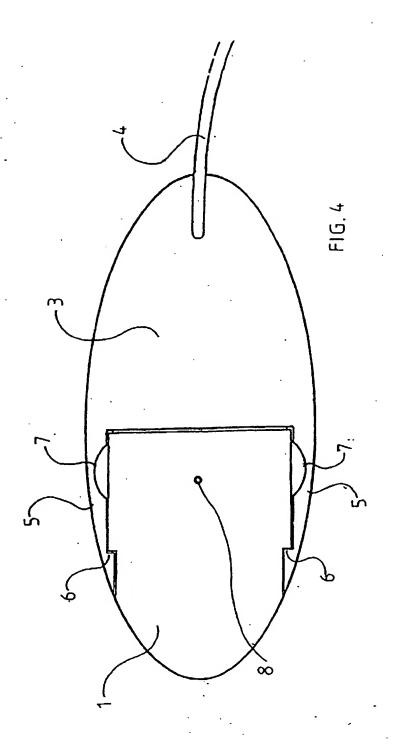
- 1. Device for subcutaneous infusion featuring the following:
  - a housing;
  - a flow channel in the housing;
  - a needle attached in the housing to the flow channel in flow connection;
  - a self-sealing partition, which covers the flow channel;
  - a connection device to supply fluids to the flow channel;
  - a needle on the connection device to penetrate the self-sealing partition, which covers the flow channel;
  - an opening in the housing to insert an insertion needle;
  - a self-sealing partition to cover the opening:

- at which the self-sealing partition, which covers the flow channel, and the self-sealing partition, which covers the opening, consist of a single element.
- 2. Device for subcutaneous infusion according to claim 1, characterized by the fact that the housing features a part of the flow channel which produces a chamber, with the opening facing the chamber and the self-sealing partition is placed in the chamber.
- 3. Device for subcutaneous infusion according to claim 1, characterized by the fact that the self-sealing partition has a surface that is inclined in relationship to the axis of the flow channel as well as to the axis through the opening and the needle.
- 4. Device for subcutaneous infusion according to claim 1, characterized by the fact that the self-sealing partition has the shape of a truncated cylinder with an angle that is inclined in relation to the centerline.
- 5. Device for subcutaneous infusion according to claim 1, characterized by the fact that the self-sealing partition has the shape of a truncated ball, for example hemispherical.



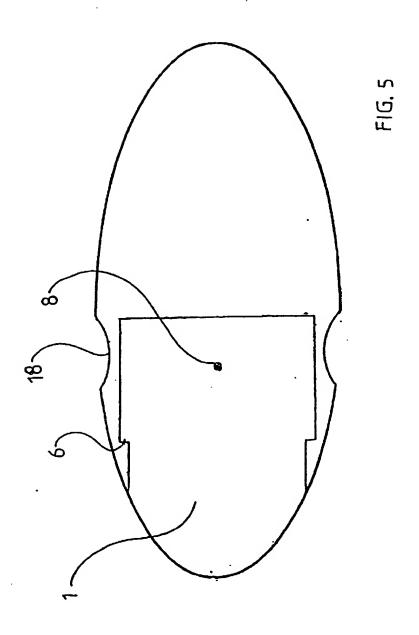


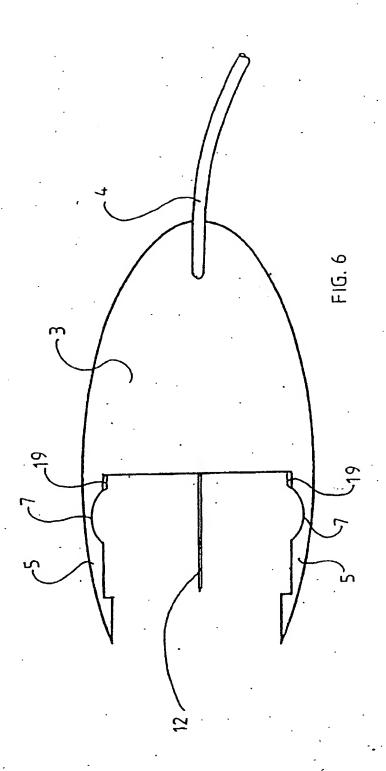


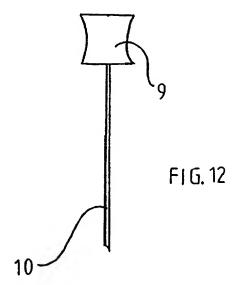


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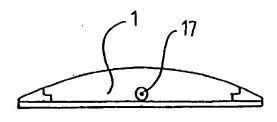
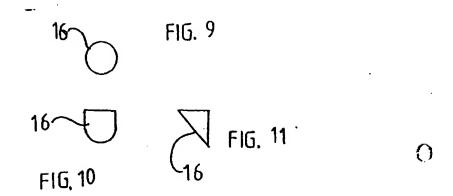


FIG. 7



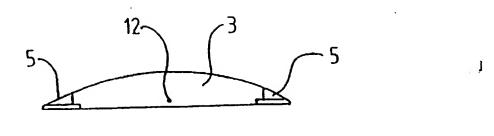
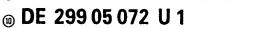


FIG. 8

- **DEUTSCHLAND**
- ® BUNDESREPUBLIK ® Gebrauchsmusterschrift
- (5) Int. Cl.6: A 61 M 25/06





**DEUTSCHES** PATENT- UND **MARKENAMT** 

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(7) Inhaber:

Maersk Medical A/S, Lynge, DK

(7) Vertreter:

Tiedtke, Bühling, Kinne & Partner, 80336 München

- Subkutane Infusionsvorrichtung
- Subkutane Infusionsvorrichtung, die folgendes aufweist:

ein Gehäuse;

einen Strömungskanal in dem Gehäuse;

eine in dem Gehäuse in Strömungsverbindung mit dem Strömungskanal befestigte Kanüle;

eine selbstdichtende Scheidewand, die den Strömungskanal abdeckt;

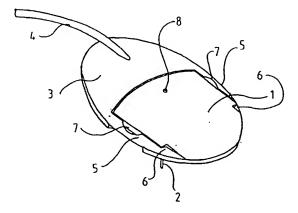
eine Verbindungsvorrichtung zur Lieferung von Hüssigkeit in den Strömungskanal;

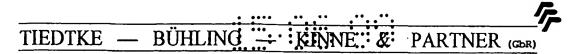
eine Nadel auf der Verbindungsvorrichtung zur Durchdringung der selbstdichtenden Scheidewand, die den Strömungskanal abdeckt;

eine Öffnung in dem Gehäuse zur Einführung einer Einführnadel;

eine selbstdichtende Scheidewand zur Abdeckung der Öffnung;

wobei die selbstdichtende Scheidewand, die den Strömungskanal abdeckt und die selbstdichtende Scheidewand, die die Öffnung abdeckt, ein einziges Element sind.





Tiedtke - Bühling - Kinne, POB 20 19 18, D - 80019 München 🧵

Patentarwälte / Vertreter beim EPA \*
Dipl.-Ing. Harro Tiedtke \*
Dipl.-Ing. Reinhard Bühling \*
Dipl.-Ing. Reinhard Kinne \*
Dipl.-Ing. Reinhard Kinne \*
Dipl.-Ing. Klaus Grams \*
Dipl.-Ing. Klaus Grams \*
Dipl.-Ing. Klaus Grams \*
Dipl.-Ing. Aurel Vollnhals \*
Dipl.-Ing. Thomas J.A. Leson \*
Dipl.-Ing. Thomas J.A. Leson \*
Dipl.-Ing. Dr. Georgi Chivarov \*
Dipl.-Ing. Matthias Grill \*
Dipl.-Ing. Matthias Grill \*
Dipl.-Ing. Alexander Kühn \*
Dipl.-Ing. Rainer Böckelen \*

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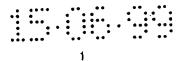
MAERSK MEDICAL A/S

Lynge, Dänemark

"Subkutane Infusionsvorrichtung"

Telefon: 089 - 544690
Telefax(G3): 089 - 532611
Telefax(G4): 089 - 5329095
postoffice@tbk-patent.com

Deutsche Bank (München) Kto. 288 1060 (BLZ 700 700 10) Dresdner Bank (München) Kto. 3939 844 (BLZ 700 800 00) Postbank (München) Kto. 670 - 43 - 804 (BLZ 700 100 80) Dal-Ichi-Kangyo Bank (München) Kto. 51 042 (BLZ 700 207 00) Sanwa Bank (Düsseldorf) Kto. 500 047 (BLZ 301 307 00)



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## Titel

#### Subkutane Infusionsvorrichtung

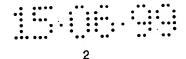
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#### Hintergrund der Erfindung

Die vorliegende Erfindung bezieht sich Infusionsvorrichtungen zur subkutanen Abgabe eines Arzneimittels oder einer therapeutischen Flüssigkeit mittels eines externen Infusionssystems und insbesondere bezieht sie sich auf eine Infusionsvorrichtung, die eine lösbar verbundene Vorrichtung zur Abgabe des Arzneimittels oder der therapeutischen Flüssigkeit von dem externe Infusionssystem hat.

- Infusionsvorrichtungen sind im Stand der Technik allgemein bekannt zur Abgabe eines Arzneimittels oder einer therapeutischen Flüssigkeit an eine subkutane Stelle in einem Patienten mittels einer Kanüle, die durch die Haut des Patienten zur der subkutanen Stelle eingeführt wird. Solche Vorrichtungen weisen für gewöhnlich eine rohrförmige Kanüle auf, die sich von einem Gehäuse aus erstreckt, das dazu angepaßt ist, das gewünschte Arzneimittel über eine trennbare Vorrichtung zur geeigneten Verbindung mit weiteren Komponenten des Infusionssystems aufzunehmen. Die Möglichkeit der Trennung des Infusionssets von den weiteren Teilen des
- 25 Infusionssystems ist vorgesehen, um den Anwenderkomfort zu verbessern. Der Anwender ist in der Lage, Aktivitäten auszuführen, die die Anwesenheit einer Pumpe oder ähnlichem nicht erlauben, oder die durch die Anwesenheit einer Pumpe oder dergleichen behindert werden. In dem getrennten Zustand wird nur ein Teil des
- Infusionssets vom Patienten getragen. Dies erlaubt eine erhöhte Mobilität. Um eine solche trennbare Vorrichtung zu schaffen und um darüber hinaus eine fluiddichte Abdichtung zu dem Inneren des Gehäuses und der rohrförmigen Kanüle aufrechtzuerhalten, die eine Kontamination der Infusionsstelle verhindert, sind solche
- 35 Vorrichtungen für gewöhnlich mit einer selbstdichtenden Scheidewand



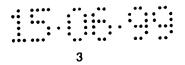
entweder auf dem Gehäuse oder auf dem trennbaren Teil versehen und mit einer hohlen Nadel auf dem anderen Teil, die dazu angepaßt ist, die Scheidewand zu durchdringen. Infolge des Herausziehens der Nadel aus der Scheidewand sorgt dies für eine fluiddichte Abdichtung zu 5 dem Inneren des Gehäuses. Die Scheidewand und die Nadel schaffen ferner eine fluiddichte Abdichtung zwischen dem Gehäuse und der Verbindungsvorrichtung, wenn das Arzneimittel oder die therapeutische Flüssigkeit von dem externen Infusionssystem an dem Patienten abgegeben wird. Subkutane Infusionsvorrichtungen dieser allgemein bekannten Art sind beispielsweise aus dem US-Patent 5522803 von Teissen-Simony und dem US-Patent 5545143 von Fischell bekannt.

In Verbindung mit solchen Infusionsvorrichtungen, die unterschiedliche Einführstellen für die Einführnadel und die Nadel der Verbindungsvorrichtung haben, muß eine selbstdichtende Scheidewand an jeder Einführstelle angeordnet sein. Die Herstellung solcher Vorrichtungen ist aufgrund dieser Tatsache ziemlich lästig und zeitaufwendig.

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Die bisher bekannten Infusionsvorrichtungen sind aufgrund ihrer Konstruktion, die eine Scheidewand an jeder Einführstelle für eine Nadel erfordert, relativ platzraubend.

Aus diesen Gründen besteht ein Bedarf an Verbesserungen in den Infusionsvorrichtungen der oben beschriebenen Bauart und insbesondere in Bezug auf das Vorsehen einer Infusionsvorrichtung, die vom Standpunkt der Herstellung aus gesehen weit weniger umständlich in Bezug zu einer Vorrichtung ist, die eine fluiddichte Abdichtung zwischen dem Gehäuse und der Verbindungsvorrichtung in einer wechselseitigen Befestigungsposition für diese Elemente ist. Die erfindungsgemäße Infusionsvorrichtung stellt die oben beschriebene Nachteile ab und schafft weitere Vorteile, die anhand der nachfolgenden Beschreibung offensichtlich werden.



### Zusammenfassung der Erfindung

Gemäß der Erfindung wurde eine subkutane Infusionsvorrichtung entwickelt, wobei die Infusionsvorrichtung folgendes aufweist:

5

ein Gehäuse;

einen Strömungskanal in dem Gehäuse;

10 eine in dem Gehäuse befestigte Kanüle in Strömungsverbindung mit dem Strömungskanal;

eine selbstdichtende Scheidewand, die den Strömungskanal abdeckt;

eine Verbindungsvorrichtung zur Abgabe von Flüssigkeit in den Strömungskanal;

eine Nadel auf der Verbindungsvorrichtung zum Durchdringen der selbstdichtenden Scheidewand, die den Strömungskanal abdeckt;

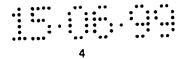
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eine Öffnung in dem Gehäuse zur Einführung einer Einführnadel;

eine selbstdichtende Scheidewand für die Abdeckung der Öffnung;

25 wobei die selbstdichtende Scheidewand, die den Strömungskanal abdeckt und die selbstdichtende Scheidewand, die die Öffnung abdeckt, ein einziges Element ist.

Durch Vorsehen der selbstdichtenden Scheidewand zum Abdichten beider Öffnungen als ein einziges Element können sowohl die Materialkosten als auch die Herstellungskosten ohne Einfluß auf die Funktion der Infusionsvorrichtung reduziert werden. Ferner wurde es ermöglicht, eine Infusionsvorrichtung zu schaffen, die kleinere Abmessungen als die bisher Bekannten hat.



In einem bevorzugten Ausführungsbeispiel weist das Gehäuse einen eine Kammer erzeugenden Teil des Strömungskanals auf, und wo die Öffnung der Kammer gegenüberliegt und wo die selbstdichtende Scheidewand in der Kammer plaziert ist.

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Als weiteren Vorteil hat die selbstdichtende Scheidewand eine Oberfläche, die sowohl im Verhältnis zur Achse des Strömungskanals als auch zur Achse durch die Öffnung und die Kanüle geneigt ist.

10 Die Infusionsvorrichtung ist vorteilhafter Weise mittels eines Klebstoffs mit dem Patienten verbunden.

Die Erfindung wird im nachfolgenden unter Bezugnahme auf die Zeichnung detaillierter erläutert.

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#### Kurze Beschreibung der Zeichnungen

Figur 1 ist eine perspektivische Ansicht eines weiteren bevorzugten Ausführungsbeispiels der erfindungsgemäßen subkutane

20 Infusionsvorrichtung;

Figur 2 ist eine Seitenansicht der in Figur 1 gezeigten Vorrichtung;

Figur 4 ist eine Draufsicht der in Figur 1 gezeigten Vorrichtung;

Figur 3 ist eine Schnittansicht entlang der Linie 3-3 in Figur 4;

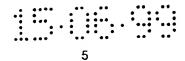
Figur 5 ist eine Draufsicht des Gehäuses der in Figur 1 gezeigten Vorrichtung;

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Figur 6 ist eine Draufsicht der Verbindungsvorrichtung der in Figur 1 gezeigten Vorrichtung;

Figur 7 ist eine Rückansicht des Gehäuses der in Figur 4 gezeigten 35 Vorrichtung;



Figur 8 ist eine vordere Endansicht der Verbindungsvorrichtung der in Figur 4 gezeigten Vorrichtung;

5 Figur 9 ist eine Draufsicht einer selbstdichtenden Scheidewand;

Figur 10 ist eine Vorderansicht einer selbstdichtenden Scheidewand;

Figur 11 ist eine Seitenansicht einer selbstdichtenden Scheidewand;

Figur 12 ist eine Seitenansicht einer Einführnadel zur Verwendung in Verbindung mit der Vorrichtung, die in Figur 1 gezeigt ist.

#### Beschreibung der bevorzugten Ausführungsbeispiele

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Aus Figur 1 geht hervor, daß das zweite Ausführungsbeispiel der Infusionsvorrichtung ein Gehäuse 1 und eine weiche Kanüle 2 aufweist, die sich von dem Gehäuse aus erstreckt. Eine Verbindungsvorrichtung 3 ist mit dem Gehäuse verbunden und ein Schlauch 4 erstreckt sich von der Verbindungsvorrichtung, um eine Fluidverbindung zwischen einer (nicht gezeigten) Pumpe und der Verbindungsvorrichtung 3 zu schaffen. Zwei Sperrarme 5 sind auf der Verbindungsvorrichtung 3 vorgesehen, um eine Sperrfunktion in Bezug zum Gehäuse 1 zu schaffen.

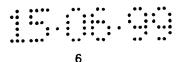
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Aus Figur 2 geht die Vorrichtung von der Seite aus gesehen hervor. Es geht daraus hervor, daß eine Einführungsvorrichtung, die eine Nadelbuchse 9 und eine Nadel 10 aufweist, in dem Gehäuse und durch das Lumen der weichen Kanüle 2 befestigt war.

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Aus Figur 3 geht hervor, daß das Gehäuse 1 mit einer Bohrung versehen ist, wobei an einem Ende dieser Bohrung die weiche Kanüle 2 in Strömungsverbindung mit der Bohrung befestigt ist. An dem Ende der Bohrung, entgegengesetzt zur weichen Kanüle 2, ist eine selbstdichtende Scheidewand 16 befestigt. Die Verbindungsvorrichtung



3 weist eine Bohrung 13 auf, wo der Schlauch 4 in Fluidverbindung mit dieser Bohrung an einem Ende davon verbunden ist, und wo am Ende der Bohrung, entgegengesetzt zum Schlauch, eine Hohlnadel 12 in Fluidverbindung mit der Bohrung vorgesehen ist. Die Nadel 12 ist zur Durchdringung der selbstdichtenden Scheidewand 16 in dem Gehäuse vorgesehen. Die selbstdichtende Scheidewand 16 sieht eine Flüssigkeits- und Luftdichtung zur Umgebung hin vor, wenn die Nadel 12 der Verbindungsvorrichtung 3 aus der Scheidewand herausgezogen wird und sie sieht ferner eine Luft- und Flüssigkeitsdichtung um die Nadel 12 herum vor, wenn sie durch die Scheidewand 16 eingeführt wird.

Aus Figur 4 geht hervor, daß die Vorrichtung eine im wesentlichen elliptische Grundform hat. Die Vorrichtung könnte jedoch irgendeine andere Grundform haben, die das Vorsehen einer Bohrung, einer selbstdichtenden Scheidewand und einer Kanüle in dem Gehäuse und einer Bohrung, eines Schlauches und einer Nadel in der Verbindungsvorrichtung und ferner der kombinierten Führungs- und Verschließvorrichtung 5, 6 in Verbindung mit dem Gehäuse und der Verbindungsvorrichtung zuläßt. Die zwei Sperrarme 5 auf der Verbindungsvorrichtung weisen jeweils einen Widerhaken 6 auf, der mit einer Kante in dem Gehäuse 1 zusammenwirkt. Um die Verbindungsvorrichtung 3 zu lösen, müssen die Sperrarme 5 an der Fläche 7, die eine reduzierte Materialdicke hat, zueinander gedrückt werden, um die Widerhaken aus der Sperrposition freizugeben, während die Verbindungsvorrichtung 3 aus dem Gehäuse 1 zurückgezogen wird.

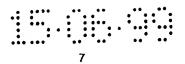
Aus Figur 5 geht das Gehäuse hervor, nachdem die

Verbindungsvorrichtung von der Vorrichtung freigegeben wurde. Es ist
zu entnehmen, daß das Gehäuse 1 eine sich nach hinten erstreckende

Plattform aufweist, die für die Abstützung der

Verbindungsvorrichtung im befestigten Zustand gedacht ist. Nuten 18
sind vorgesehen, um die Bewegung der Sperrarme zueinander während
einem Lösevorgang der Verbindungsvorrichtung zu erleichtern.

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Aus Figur 6 geht die Verbindungsvorrichtung 3 hervor, nachdem sie von dem Gehäuse 1 gelöst wurde. Es geht daraus hervor, daß sich die flexiblen Sperrarme 5 über die Nadel 12 hinaus erstrecken, wodurch ein Schutzschild gegen schädliche Verletzungen, die durch die Nadel hervorgerufen werden, vorgesehen wird. Ferner sind Vorsprünge 19 auf jedem Arm vorgesehen. Diese dienen als Führungsvorrichtung für die Verbindungsvorrichtung in Bezug zum Gehäuse und verhindern unbeabsichtigte Bewegungen guer zur Nadelachse.

10 Aus Figur 7 geht das hintere Ende des Gehäuses hervor. Der konische Eingang für die Nadel in das Element 17 wird dargestellt, ebenso wie die Nuten für die flexiblen Führungs- und Sperrarme 5, 19.

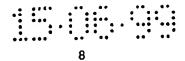
Aus Figur 8 geht das vordere Ende der Verbindungsvorrichtung 3 15 hervor. Die Nadel 12 und die flexiblen Führungs- und Sperrarme 5 sind sichtbar.

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Aus Figur 9, Figur 10 und Figur 11 geht jeweils die selbstdichtende Scheidewand 16 in Draufsicht, Vorderansicht und Seitenansicht hervor. Die Scheidewand 16 hat auf der äußeren Seite die Gestalt eines schrägen abgeschnittenen Zylinders. Es geht daraus hervor, daß die Scheidewand aufgrund der schrägen, abgeschnittenen Gestalt, eine Oberfläche aufweist, die im Verhältnis zur flachen Oberseite und zur Rückseite abgeschrägt ist. Die geneigte Oberfläche zeigt zum Inneren des Gehäuses und erlaubt das Durchdringen der Einführnadel in und durch die weiche Kanüle und den Einsatz der Nadel der Verbindungsvorrichtung, um Flüssigkeit in den Hohlraum im Inneren des Gehäuses zu liefern. Die Scheidewand kann jedoch irgendeine Gestalt haben, die mit dem Gehäuse um die jeweiligen Öffnungen herum übereinstimmt und die zur gleichen Zeit die Durchdringung von sowohl der Einführnadel als auch der Nadel der Verbindungsvorrichtung zuläßt, beispielsweise eine teilweise kugelförmige Gestalt.

Aus Figur 12 geht eine Einführnadel zur Verwendung in Verbindung mit 35 der in Figur 10 gezeigten Vorrichtung hervor. Die Einführnadel weist



eine Nadelbuchse 9 und eine Nadel 10 auf, die sich in der Einführposition, die in Figur 2 gezeigt ist, durch die weiche Kanüle 2 über die äußere Spitze dieser hinaus erstreckt.

Die Erfindung bezieht sich auf eine subkutane Infusionsvorrichtung, die folgendes aufweist: ein Gehäuse; einen Strömungskanal in dem Gehäuse; eine in dem Gehäuse in Strömungsverbindung mit dem Strömungskanal befestigte Kanüle; eine selbstdichtende Scheidewand, die den Strömungskanal abdeckt; eine Verbindungsvorrichtung zur

10 Lieferung einer Flüssigkeit in den Strömungskanal; eine Nadel auf der Verbindungsvorrichtung zum Durchdringen der selbstdichtenden Scheidewand, die den Strömungskanal abdeckt; eine Öffnung in dem Gehäuse zur Einführung einer Einführnadel; eine selbstdichtende Scheidewand zur Abdeckung der Öffnung; wobei die selbstdichtende

15 Scheidewand, die den Strömungskanal abdeckt, und die selbstdichtende Scheidewand, die die Öffnung abdeckt, ein einziges Element sind.

Durch Vorsehen des selbstdichtenden Elements zur Abdichtung beider Öffnungen als ein einziges Abdichtungselement können sowohl die Materialkosten als auch die Herstellungskosten ohne Einfluß auf die Funktion der Infusionsvorrichtung reduziert werden.

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# TIEDTKE - BUHLING : KINNE: & PARTNER (GbR)

9

☐ Tledtke-Bühling-Kinne, POB 20 19 18, D-80019 München ☐

Patentanwälte / Vertreter beim EPA

Dipl.-Ing. Harro Tiedtke'
Dipl.-Chem. Gerhard Bühling'
Dipl.-Ing. Reinhard Kinne'
Dipl.-Ing. Hans-Bernd Pellmann'
Dipl.-Ing. Klaus Grams'
Dipl.-Biol. Dr. Annette Link
Dipl.-Ing. Aure! Voltnhals'
Dipl.-Ing. Thomas J. A. Leson'
Dipl.-Ing. Hans-Ludwko Trösch'

Dipl.-Ing. Thomas J. A. Leson' Dipl.-Ing. Hans-Ludwig Trösch' Dipl.-Ing. Dr. Georgi Chivarov' Dipl.-Ing. Matthias Grill'

Dipl.-Ing. Alexander Kühn\* Dipl.-Chem. Dr. Andreas Oser\* Dipl.-Ing. Rainer Böckelen\*

Bavarlaring 4, D-80336 München

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DE 23838/case P199701455 DE 15. Juni 1999

#### Schutzansprüche

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Subkutane Infusionsvorrichtung, die folgendes aufweist:

ein Gehäuse;

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einen Strömungskanal in dem Gehäuse;

eine in dem Gehäuse in Strömungsverbindung mit dem Strömungskanal befestigte Kanüle;

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eine selbstdichtende Scheidewand, die den Strömungskanal abdeckt;

eine Verbindungsvorrichtung zur Lieferung von Flüssigkeit in den Strömungskanal;

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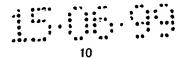
eine Nadel auf der Verbindungsvorrichtung zur Durchdringung der selbstdichtenden Scheidewand, die den Strömungskanal abdeckt;

eine Öffnung in dem Gehäuse zur Einführung einer Einführnadel;

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eine selbstdichtende Scheidewand zur Abdeckung der Öffnung;

Telefon: 089-544690 Telefax(G3): 089-532611 Telefax(G4): 089-5329095 postoffice@tbk-patent.com Deutsche Bank (München) Kto. 288 1060 (BLZ 700 700 10) Drasdner Bank (München) Kto. 3939 844 (BLZ 700 800 00) Postbank (München) Kto. 670-43-604 (BLZ 700 100 80) Dei-Ichi-Kangyo Bank (München) Kto. 51 042 (BLZ 700 207 00) Sanwa Bank (Düsseldori) Kto. 500 047 (BLZ 301 307 00)



wobei die selbstdichtende Scheidewand, die den Strömungskanal abdeckt und die selbstdichtende Scheidewand, die die Öffnung abdeckt, ein einziges Element sind.

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2. Subkutane Infusionsvorrichtung gemäß Anspruch 1, dadurch gekennzeichnet, daß das Gehäuse einen eine Kammer erzeugenden Teil des Strömungskanals aufweist, und daß die Öffnung der Kammer gegenüberliegt und daß die selbstdichtende Scheidewand in der Kammer plaziert ist.

3. Subkutane Infusionsvorrichtung gemäß Anspruch 1, dadurch gekennzeichnet, daß die selbstdichtende Scheidewand eine Oberfläche hat, die sowohl im Verhältnis zur Achse des Strömungskanals als auch zur Achse durch die Öffnung und die Kanüle geneigt ist.

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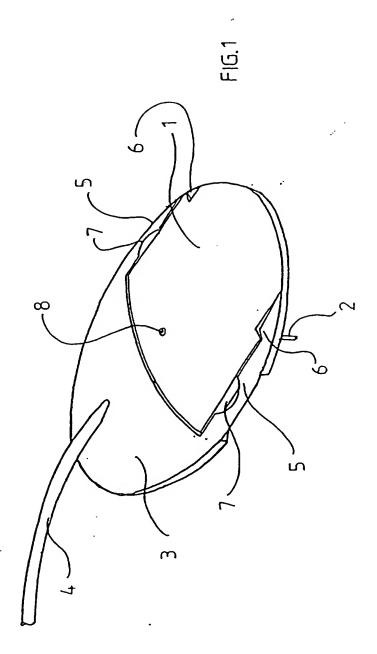
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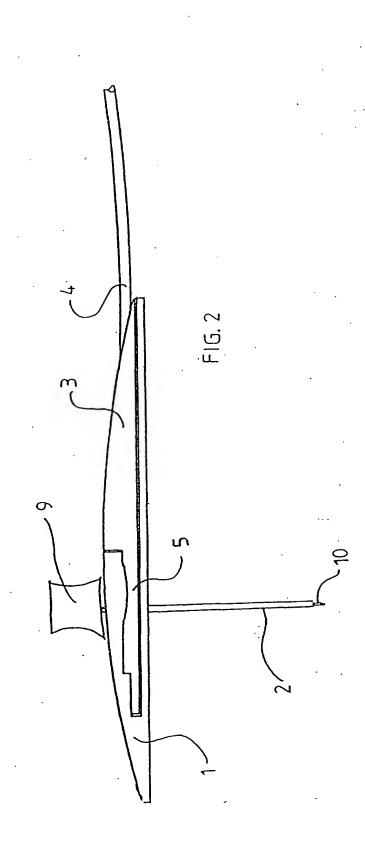
4. Subkutane Infusionsvorrichtung gemäß Anspruch 1, dadurch gekennzeichnet, daß die selbstdichtende Scheidewand eine Gestalt eines abgeschnittenen Zylinders mit einem schrägen Winkel im Verhältnis zur Mittelachse hat.

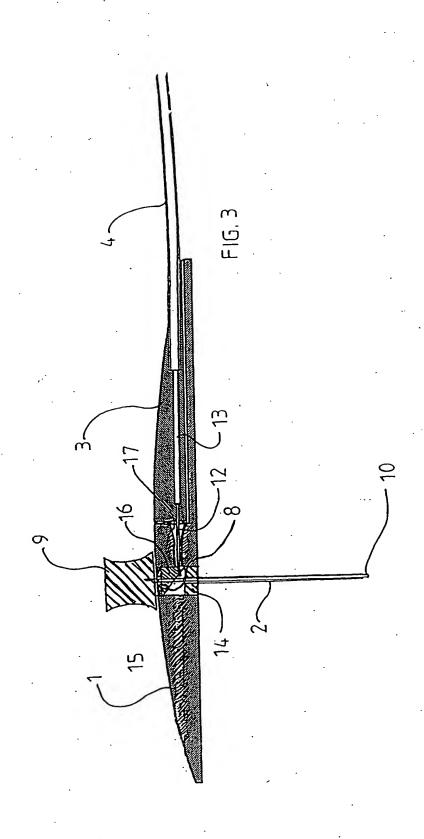
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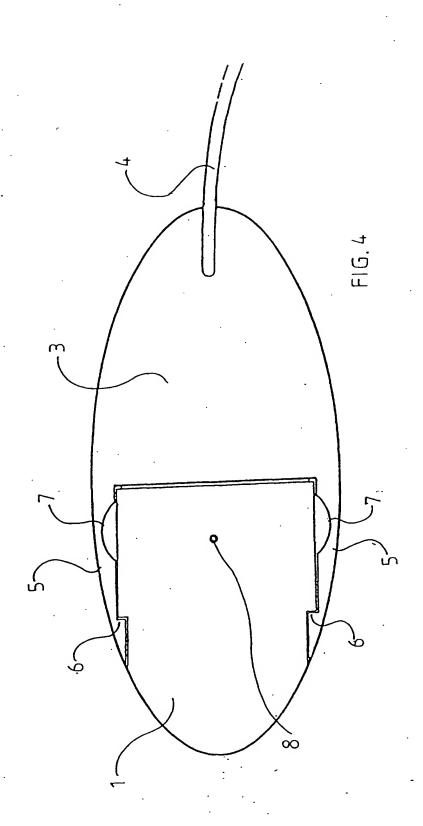
5. Subkutane Infusionsvorrichtung gemäß Anspruch 1, dadurch gekennzeichnet, daß die selbstdichtende Scheidewand die Gestalt einer abgeschnittenen Kugel, beispielsweise einer Halbkugel hat.

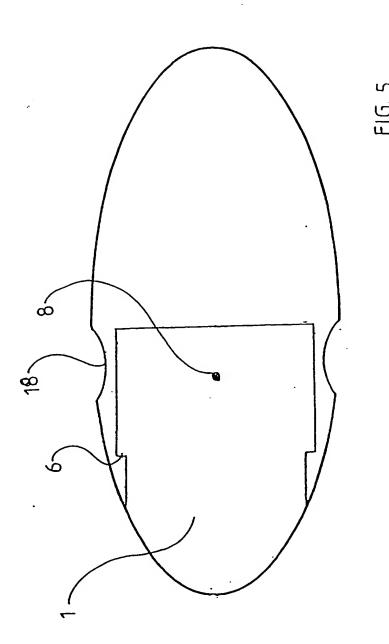
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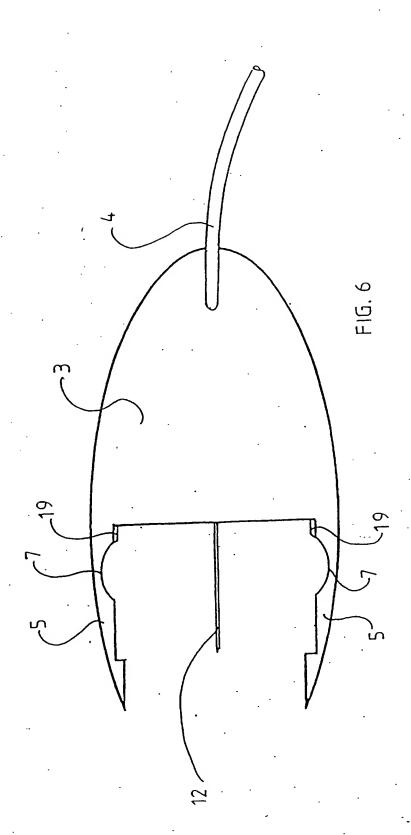




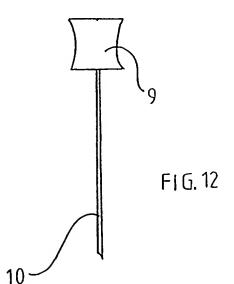


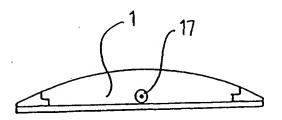








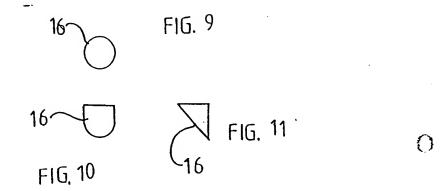




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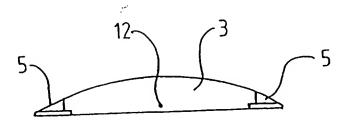


FIG. 8

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(73) Owner:

Maersk Medical A/S, lynge, DK

74) Representative

Tiedtke, Bühling, Kinne & Partner, 80336 Munich

#### (54) Device for subcutaneous infusion

(57) Device for subcutaneous infusion featuring the following:

a housing;

a flow channel inside the housing;

a needle attached in the housing to the flow channel in flow connection;

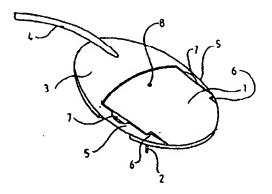
a self-sealing partition, which covers the flow channel;

a connection device to supply fluids to the flow channel;

a needle on the connection device to penetrate the self-sealing partition, which covers the flow

an opening in the housing to insert an insertion needle;

a self-sealing partition to cover the opening; at which the self-sealing partition, which covers the flow channel, and the self-sealing partition, which covers the opening, consist of a single element.



# TIEDTKE --- BÜHLING --- KINNE & PARTNER (GbR)

Tiedtke -- Bühling -- Kinne, POB 20 19 18, D-80019 Munich

Patent Attorneys / Representatives at EPO \*

Dipl. Ing. Harro Tiedtke\*

Dipl. Chem. Gerhard Bühling\*

Dipl. Ing. Reinhard Kinne

Dipl. Ing. Hans-Bernd Pellmann\*

Dipl. Ing. Klaus Grams\*

Dipl. Biol. Dr. Annette Link

Dipl. Ing. Aurel Volinhals\*

Dipl. Ing. Thomas J. A. Leson\*

Dipl. Ing. Hand-Ludwig Trösch\*

Dipl. Ing. Dr. Georgi Chivarov\*

Dipl. Ing. Matthias Grill\*

Dipl. Ing. Alexander Kühn\*

Dipl. Chem. Dr. Andreas Oser\*

Dipl. Ing. Rainer Böckelen\*

Bavariaring 4, D-80336 Munich

June 15, 1999

DE 23838 / case P199701455

# MAERSK MEDICAL A/S

Lynge, Denmark

"Device for Subcutaneous Infusion"

#### Title

#### Device for Subcutaneous Infusion

## Background of the Invention

The invention at hand is based on infusion devices for subcutaneous release of a drug or therapeutic fluid by means of an external infusion system and, in particular, is based on an infusion device which involves a device for the purpose of releasing the drug or therapeutic fluid that is detachably connected to the external infusion system.

The infusion systems generally known in prior art release a drug or therapcutic fluid to a subcutaneous area in a patient by means of a needle, which is inserted to the subcutaneous area through the patient's skin. Such devices usually have a tubular needle extending from a housing which is adapted to receive the desired drug via a detachable device which can be appropriately connected with other components of the infusion system. The possibility of detaching the infusion set from other components of the infusion system has been provided in order to make it more convenient for the user. The user is able to perform activities which do not allow for the presence of a pump or the like, or which are impeded by the presence of a pump or the like. In detached condition, the patient carries only part of the infusion set. This allows for more mobility. In order to provide such a detachable device and, in addition, maintain a fluid-proof sealing in the internal of the housing and tubular needle, which prevents contamination of the infusion area, such devices are usually provided with a self-sealing partition on the housing or on the detachable part and with a hollow needle on the other part which is adapted in such a way that it can penetrate the partition. As a result of extracting the needle from the partition, this provides a fluid-proof sealing toward the internal of the housing. Furthermore, the partition and the needle provide a fluid-proof sealing between the housing and the connection device, if the drug or the therapeutic fluid is dispensed from the external infusion system to the patient. Devices for subcutaneous infusion of this generally known kind are, for instance, known from the US patent 5522803 by Teissen-Simony and the US patent 5545143 by Fischell.

In connection with such infusion devices, which have various insertion places for the insertion needle and the needle of the connection device, a self-sealing partition is required at every insertion place. Because of this fact, manufacture of such devices is very inconvenient and time-consuming.

Because of their construction, the previously known infusion devices, which require a partition at each insertion place to insert a needle, need relatively much space.

For these reasons, there is a demand for improvement regarding infusion devices of the models described above and especially with regard to providing an infusion device which, from the viewpoint of manufacturing, is considerably less complicated than a device that has a fluid-proof sealing

between the housing and the connection device in an interactive attachment position for these elements. The invention-based infusion device eliminates the disadvantages described above and provides further advantages which are manifested by the following description.

#### Abstract of the Invention

According to the invention, a device for subcutaneous infusion has been developed at which the infusion device has the following features:

a housing;

a flow channel in the housing;

a needle attached in the housing to the flow channel in flow connection;

a self-sealing partition, which covers the flow channel;

a connection device to supply fluids to the flow channel;

a needle on the connection device to penetrate the self-sealing partition, which covers the flow channel:

an opening in the housing to insert an insertion needle;

a self-sealing partition to cover the opening;

at which the self-sealing partition, which covers the flow channel, and the self-sealing partition, which covers the opening, consist of a single element.

By providing the self-sealing partition for the purpose of sealing both openings as a single element, it is possible to reduce the cost of material as well as production cost without affecting the function of the infusion device. It also makes it possible to provide an infusion device with smaller dimensions than previously known devices.

In a preferred embodiment, the housing features a part of the flow channel which produces a chamber, with the opening facing the chamber and the self-sealing partition is placed in the chamber.

A further advantage is the fact that the self-sealing partition has a surface that is inclined in relationship to the axis of the flow channel as well as to the axis through the opening and the needle.

The infusion device is advantageously connected to the patient by means of an adhesive.

With reference to the drawings, the invention is subsequently described in more detail.

### Brief description of the drawings

Figure 1 is a perspective view of a further preferred embodiment of the invention-based device for subcutaneous infusion;

Figure 2 is a lateral view of the device shown in figure 1;

Figure 4 is a top view of the device shown in figure 1;

Figure 3 is a cross section along the line 3-3 in figure 4;

Figure 5 is a top view of the housing of the device shown in figure 1;

Figure 6 is a top view of the connection device of the device shown in figure 1;

Figure 7 is a rear view of the housing of the device shown in figure 4;

Figure 8 is a front end view of the connection device of the device shown in figure 4;

Figure 9 is a top view of the self-sealing partition;

Figure 10 is a front view of the self-sealing partition;

Figure 11 is a lateral view of the self-scaling partition;

Figure 12 is a lateral view of an insertion needle to be used in connection with the device shown in figure 1.

#### Description of the preferred embodiments

Figure 1 shows that the second embodiment of the infusion device features a housing 1 and a soft needle 2 which extends from the housing. A connection device 3 is connected to the housing and a tube 4 extends from the connection device in order to provide a fluid connection between a pump (not shown) and the connection device 3. Two blocking arms 5 are provided on the connection device 3 in order to produce a block function with regard to the housing 1.

Figure 2 shows the device from a lateral point of view. It is shown that an insertion device featuring a needle bush 9 and a needle 10 are attached in the housing and through the lumen of the soft needle 2.

Figure 3 shows that the housing 1 has a drill hole at which the soft end of the needle 2 is attached to one end of the drill hole in flow connection. Opposite of the soft needle 2, a self-sealing

partition 16 is attached to the one end of the drill hole. The connection device 3 features a drill hole 13 at which the tube 4 is connected to one end of this drill hole, forming a fluid connection. At the other end of the drill hole, opposite of the tube, a hollow needle 12 is provided, forming a fluid connection with the drill hole. The needle 12 is provided to penetrate the self-sealing partition 16 in the housing. The self-sealing partition 16 provides a fluid and air seal toward the surrounding area if the needle 12 of the connection device is extracted from the partition. Said self-sealing partition also provides a fluid and air seal around the needle 12 if it is inserted through the partition.

Figure 4 shows that the device has basically an elliptic shape. However, the device could also have any other basic shape which allows for the provision of a drill hole, a self-sealing partition and a needle in the housing, and a drill hole, a tube and a needle in the connection device and, furthermore, the combined guiding and closing device 5, 6 in connection with the housing and the connection device. Each of the two blocking arms 5 on the connection device features a barbed hook 6 which interacts with one lug in the housing 1. In order to disconnect the connection device 3 and release the barbed hooks from their blocking position while the connection device 3 is extracted from the housing 1, the blocking arms 5 must be pressed together at the surface 7 which has a tapering thickness of the material.

Figure 5 shows the housing after the connection device is released from the device. It is shown that the housing 1 features a platform which extends to the rear and which is provided to support the connection device in attached condition. Grooves 18 are provided in order to ease the movement of the blocking arms toward each other during the release action of the connection device.

Figure 6 shows the connection device after being disconnected from the housing 1. This shows that the flexible blocking arms 5 extend beyond the needle 12 providing a shield against dangerous injuries caused by the needle. Each arm also provides lugs 19. These serve as guiding devices for the connection device with regard to the housing and prevent accidental movements lateral to the needle axis.

Figure 7 shows the rear end of the housing. It is shown the conical inlet to insert the needle into the element 17, as well as the grooves for the flexible guiding and blocking arms 5, 19.

Figure 8 shows the front end of the connection device 3. It shows the needle 12 and the flexible guiding and blocking arms 5.

Figure 9, figure 10 and figure 11 each show a top view, front view and lateral view of the self-sealing partition 16. On the outside, the partition 16 has the shape of an inclined, truncated cylinder. This shows that, because of the inclined, truncated shape, the partition features a surface which is conical in proportion to the flat top side and rear side. The inclined surface points to the interior of the housing and allows the insertion needle to penetrate through the soft needle and allows the needle of the connection device to be used to supply fluid to the hollow space in the interior of the housing. However, the partition can have any shape corresponding to the respective

openings of the housing and, at the same time, allowing for the penetration of the insertion needle as well as the needle of the connection device, for example a partially ball-shaped form.

Figure 12 shows an insertion needle to be used in connection with the device shown in figure 10. The insertion needle features a needle bush 9 and a needle 10 which extends in insertion position shown in figure 2 through the soft needle 2 beyond its outer tip.

The invention applies to a device for subcutaneous infusion with the following features: a housing; a flow channel in the housing; a needle attached in the housing to the flow channel in flow connection; a self-sealing partition, which covers the flow channel; a connection device to supply fluids to the flow channel; a needle on the connection device to penetrate the self-sealing partition, which covers the flow channel; an opening in the housing to insert an insertion needle; a self-sealing partition to cover the opening; at which the self-sealing partition, which covers the flow channel, and the self-sealing partition, which covers the opening, consist of a single element.

By providing the self-sealing partition for the purpose of sealing both openings as a single element, it is possible to reduce the cost of material as well as production cost without affecting the function of the infusion device.

# TIEDTKE --- BÜHLING --- KINNE & PARTNER (GbR)

Tiedtke -- Bühling -- Kinne, POB 20 19 18, D-80019 Munich

Patent Attorneys / Representatives at EPO \*

Dipl. Ing. Harro Tiedtke\*

Dipl. Chem. Gerhard Bühling\*

Dipl. Ing. Reinhard Kinne

Dipl. Ing. Hans-Bernd Pellmann\*

Dipl. Ing. Klaus Grams\*

Dipl. Biol. Dr. Annette Link

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Dipl. Ing. Thomas J. A. Leson\*

Dipl. Ing. Hand-Ludwig Trösch\*

Dipl. Ing. Dr. Georgi Chivarov\*

Dipl. Ing. Matthias Grill\*

Dipl. Ing. Alexander Kühn\* Dipl. Chem. Dr. Andreas Oser\*

Dipl. Ing. Rainer Böckelen\*

Bavariaring 4, D-80336 Munich

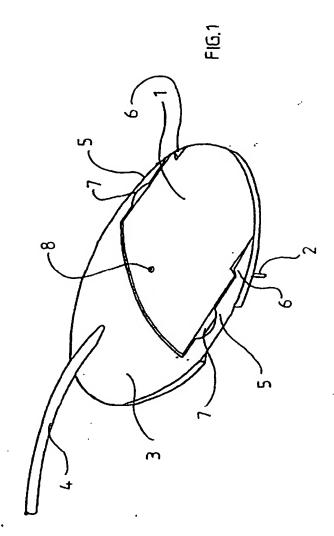
DE 23838 / case P199701455 DE June 15, 1999

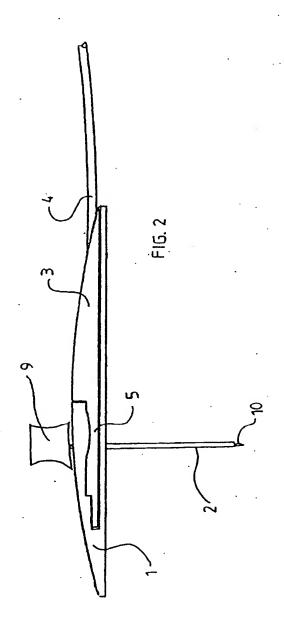
## Claims

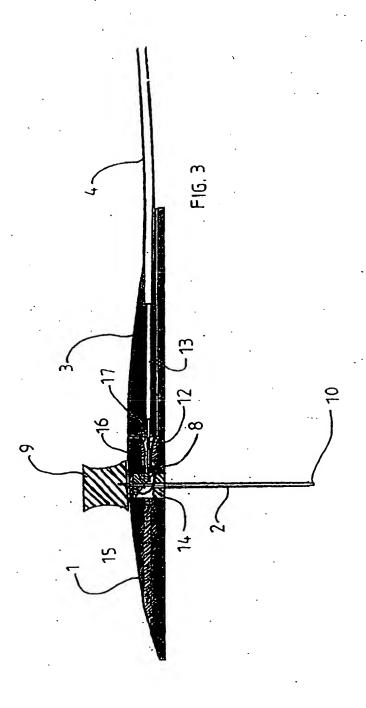
- 1. Device for subcutaneous infusion featuring the following:
  - a housing:
  - a flow channel in the housing;
  - a needle attached in the housing to the flow channel in flow connection;
  - a self-sealing partition, which covers the flow channel;
  - a connection device to supply fluids to the flow channel;
  - a needle on the connection device to penetrate the self-sealing partition, which covers the flow channel;
  - an opening in the housing to insert an insertion needle;
  - a self-sealing partition to cover the opening;

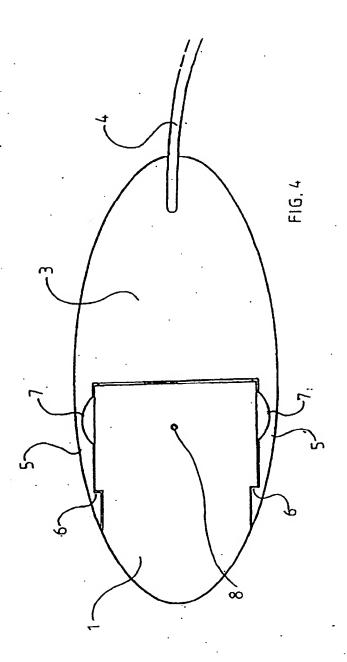
at which the self-sealing partition, which covers the flow channel, and the self-sealing partition, which covers the opening, consist of a single element.

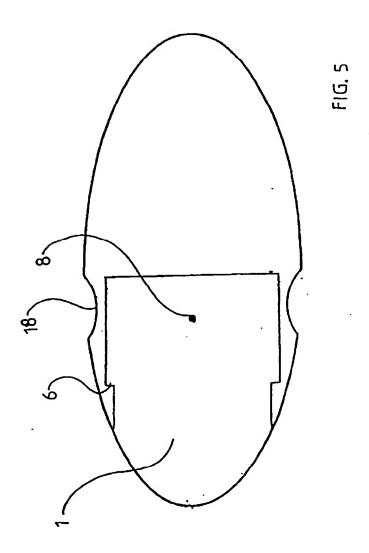
- 2. Device for subcutaneous infusion according to claim 1, characterized by the fact that the housing features a part of the flow channel which produces a chamber, with the opening facing the chamber and the self-sealing partition is placed in the chamber.
- 3. Device for subcutaneous infusion according to claim 1, characterized by the fact that the self-sealing partition has a surface that is inclined in relationship to the axis of the flow channel as well as to the axis through the opening and the needle.
- 4. Device for subcutaneous infusion according to claim 1, characterized by the fact that the self-sealing partition has the shape of a truncated cylinder with an angle that is inclined in relation to the centerline.
- 5. Device for subcutaneous infusion according to claim 1, characterized by the fact that the self-sealing partition has the shape of a truncated ball, for example hemispherical.

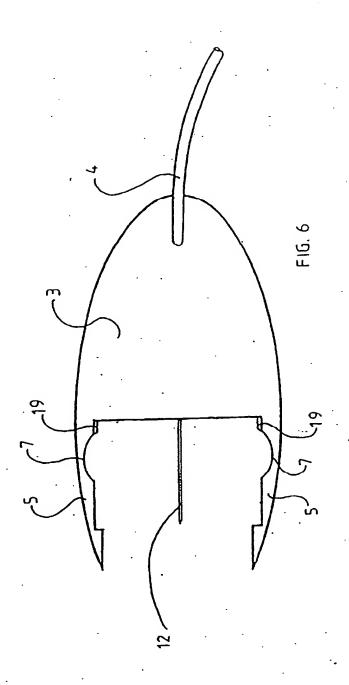


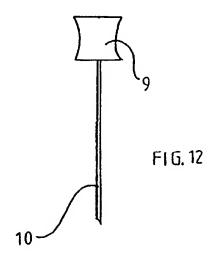












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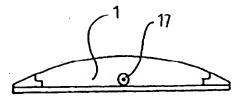


FIG. 7

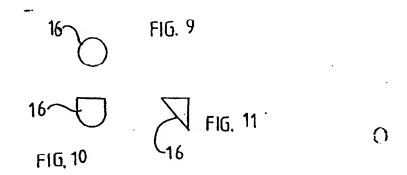




FIG. 8